Magnetically Guided Atherectomy

Cross Reference to Related Application

This application is a continuation of U.S. Patent Application Serial No. 09/352,161 filed July 12, 1999, incorporated herein by reference.

Field of the Invention

The present invention relates generally to the removal of occlusive material from body lumens, and more particularly both methods and devices for magnetically guided atherectomy of totally occluded arterial vasculature. Catheters which employ thermal as well as other energy sources are disclosed along with complementary equipment for carrying out the procedures.

Description of the Prior Art

Arteriolosclerosis is a progressive disease marked by deposits within the lumen of arterial vessels. Removal of these deposits restores blood flow and is a preferred treatment for this disease. In instances where the vessel cannot be salvaged, bypass grafts may be used to treat the disorder.

A wide range of recannalization techniques have been developed over time. The primary technique in clinical use today is balloon angioplasty. This is a "mechanical" treatment where a balloon at the treatment site is inflated to compress obstructive material against the vessel wall. In most treatment protocols the recannalization device is navigated to the treatment site through the patent's vasculature. The so-called "Seldinger" technique is used most often to gain access to and navigate through the blood vessels. In this technique the catheter enters the body in the groin area and is moved through the vasculature to the heart with the assistance of both guide wire and occasionally guide catheters or sheaths.

Although balloon angioplasty is probably the most common procedure, there are several drawbacks to this type of device. One problem is that the vascular occlusion must first be crossed with a guide wire to position the balloon. The balloon device follows the guide wire through the lesion and the wire biases the balloon against the walls of the vessel. If the vessel is totally occluded the wire cannot cross the lesion and therefore cannot be used to guide the balloon.

Energy sources for recannalization have been proposed and studied as well. For example, Carter, U.S. Patent No. 5,318,014, (incorporated herein by reference), teaches a device to treat occlusions with ultrasound. Drasler, U.S. Patent No. 5,370,609, (incorporated herein by reference) teaches the use of a high-energy rearward facing water jet to remove occlusive material. The art also teaches the use of rotating mechanical burrs or blades for removing material. See for example Pannek, U.S. Patent No. 5,224,945 (incorporated herein by reference). Also the use of heat to reform and remodel a vessel is known from Eggers, U.S. Patent No. 4,998,933, among others.

Summary

The atherectomy devices according to the invention include a magnetic element that allows for the remote manipulation of the distal end of working tip of the device by a magnetic surgery system (MSS) or other magnetic field generator operated outside of the patient.

The application of external fields and gradients allows the physician to control the orientation and location of the distal tip of the catheter in the vessel at the treatment site. This permits the use of small and potentially single size catheters to treat either partial or total occlusions in the vasculature. In operation the device is moved to various treatment sites or locations in a vessel under the guidance of the MSS. The methods of the invention may be partially automated in the sense that the physician can image the current location of the device and program a desired location with the MSS and designate a location or orientation of the device in a vessel. The MSS system can provide feedback to the physician to help the physician direct the device as "planned" with the MSS workstation. Robotic control of the device is also contemplated wherein the motion of the device in the vessel is entirely under software control. In this instance physician observation and transducer feedback manages the procedure.

Any of a variety of energy sources can be used to carry out the recannalization process of the invention, although thermal energy is preferred and is used as an illustrative energy source. The source of heat may include optical or radio frequency energy sources. However, the device is also useful with hydraulic energy, direct laser sources, ultrasonic energy sources, or mechanical energy sources. Physician supplied energy is contemplated as well in the sense that a doddering wire may be manipulated by the physician and guided magnetically to treat the occlusion.

Devices which rely on heat or which generate heat in the body may include fluid cooling to manage the distribution of heat, several device with adjunctive fluid delivery are shown as illustrative of the invention.

Additional "delivery" structures are present in some embodiments of the device and may be used to accommodate various medical techniques and methods. For example lumens for "over the wire" and "rapid exchange" delivery of the catheters are shown. Also these lumens may be used with imaging and localization devices to carry out the methods of the invention. These lumens may also be used to introduce contrast agent into the treatment site.

Localization structures are disclosed for use in the procedure. Preoperative Magnetic Resonance Imaging (MRI), Computed Tomography (CT) or Ultrasound scans provide a "roadmap" for the procedure while X-ray, Doppler ultrasound, or other localization techniques are used to display the current real time position of the device in the lumen.

It is also contemplated that the "open" lumens of the device can be used with ultrasonic, optical coherence tomographic, or laser based imaging systems to characterize the nature of the occlusion.

Brief Description of the Drawings

Throughout the various figures of the drawing like reference numerals refer to identical structure. A typical and exemplary set of embodiments of the invention are shown in the drawing but various changes to the devices may be made without departing from the scope of the invention wherein:

Fig. 1 is schematic diagram of a thermal catheter in a vessel;

Fig. 2 is a schematic diagram of a bipolar thermal catheter;

Fig. 3 is a schematic diagram of a resistance heated thermal catheter;

Fig. 4 is a schematic of a laser-heated catheter;

Fig. 5 is a schematic of a thermal catheter having an additional lumen;

Fig. 6 is a RF heated catheter with a rapid exchange lumen;

Fig. 7 is an ultrasound atherectomy device driven by an external horn;

Fig. 8 is a hydraulic catheter;

Fig. 9 is an optically heated catheter in a sheath;

Fig. 10 is an optically heated device with an auxiliary lumen;

Fig. 11 is an optically heated device with multiple lumens;

Fig. 12 is an optically heated device with a distal port; and

Fig. 13 is a schematic overview of the automated workstation.

Fig. 14 is an exploded perspective view of a second embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 15 is a longitudinal cross-sectional view of the distal end portion of the magnetically guided atherectomy device of the second embodiment;

Fig. 16 is a perspective view of the distal end portion of the magnetically guided atherectomy device of the second embodiment;

Fig. 17 is an exploded perspective view of a third embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 18 is a longitudinal cross-sectional view of the distal end portion of the magnetically guided atherectomy device of the third embodiment;

Fig. 19 is a perspective view of the distal end portion of the magnetically guided atherectomy device of the third embodiment;

Fig. 20 is an exploded perspective view of a fourth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 21 is a longitudinal cross-sectional view of the distal end portion of the magnetically guided atherectomy device of the fourth embodiment;

Fig. 22 is a longitudinal cross-sectional view of a first alternate construction of a fifth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 23 is a longitudinal cross-sectional view of a second alternate construction of a fifth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 24 is a longitudinal cross-sectional view of a third alternate construction of a fifth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 25 is a longitudinal cross-sectional view of a first alternate construction of a sixth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention;

Fig. 26 is a longitudinal cross-sectional view of a second alternate construction of a sixth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention; and

Fig. 27 is a longitudinal cross-sectional view of a third alternate construction of a sixth embodiment of a magnetically guided atherectomy device constructed according to the principles of this invention.

Detailed Description the Invention

Fig. 1 shows a thermal catheter 10 in a vessel 12. The distal tip section 14 of the device is shown in a vessel while the proximal section 15 is illustrated as a fragment located outside of the vessel 12. In general, the construction of the proximal end of the device and configuration and power couplings are within the ordinary skill of this art and are illustrated schematically in Fig. 1. For clarity the detailed disclosure is directed to the

distal tip structures. However it should be recognized that the devices are intended for use in coronary vessels, the overall length of devices in accordance with this invention are 30 or more inches long and typical are between 2 and 12 French in diameter. It should be understood that coronary use is merely illustrative and other vessels and body lumens may be addressed therapeutically using the invention. The proximal end will carry suitable hubs and connections for the wires and lumens discussed in connection with the distal tip.

In Fig. 1 the distal tip 14 of the catheter 10 abuts a total occlusion 16. A guide wire 18 shown in phantom, and sheath 20 may be used together to deliver the catheter 10 to the treatment site near the occlusion 16. Either or both of the guide wire or sheath may have a magnetic element 22 included in its design to assist in access to the treatment site. For instance the guide wire 18 may have a magnet 22 located at its distal tip. Similarly the sheath may have a magnetic tube 24 located at its distal tip. However, for the purpose of this disclosure the magnetic elements on the guide wire or sheath permit the applied field or gradient to orient the distal tip. In Fig. 1 the forces generated on the tip by an external magnet are shown by vectors indicated by reference numeral 9. The physician can advance the guide wire or sheath by pushing on the proximal end of end of the device with the distal tip direction determined in part by the magnetic forces represented at 9. The magnetic orientation of the tip coupled with physical motion applied to the proximal end of the device positions the device. The physical motion can be supplied by either the physician or a robotic element.

The thermal catheter embodiment of Fig. 1 has a heated tip 26. Preferably this tip is formed from Hiperco or other magnetically active metallic material. In this context iron-containing alloys of steel which are attracted to magnets are suitable choices for the tip material. Although the distal tips are shown in hemispheric in shape for consistency of explanation it should be understood that other forms and shapes are operable so the shape should be understood as illustrative and not limiting. In use heat is delivered by the tip 26. More specifically the tip generates heat in the tissue distal to the tip. The lines located by reference numeral 38 represent heat transfer to the occlusion 16, which allows the tip 26 to move through the occlusion 16. In this embodiment the tip 26 is heated with RF energy from an RF source 28. The RF source is coupled to the tip by a wire 32. A patch electrode 34 having a large area may be placed on the patient to complete the circuit to the RF source 28 through wire 36. This configuration may be called "monopolar" in contrast to the "bipolar configuration shown in Fig. 2. A coating 27 may be applied to the surface of the distal tip to prevent sticking or adhesions. The coating 27 may also increase biocompatibility or improve heat transfer through the device. Both polymeric materials such as Teflon and metallic materials such as titanium nickel alloy are suitable for this application. Therefore the illustrative embodiments of the invention should be considered to be "composite" constructions where individual elements may be made of more than one material as indicated by coating 29.

Fig. 2 shows a distal tip embodiment for a thermal catheter 10, which includes two metal structures that are insulated from each other. The first structure is the distal tip 40 which is metal and may be magnetically active. The wire 32 couples this tip to the RF source 28. The second element is the return electrode 42. Preferably this function is served by metallic ring or bank 42 which is coupled to the RF source 28 through the wire 36. In this embodiment one or both of the metallic elements may be magnetically active. Also partial rings which surround only part of the catheter are contemplated within the scope of the invention although they are not preferred. In general the exact shape of the distal rings will not be critical to the operation of the invention.

Fig. 3 shows a resistance-heated embodiment of a thermal catheter 10 where the distal tip 44 is magnetically active metal. The tip 44 is electrically isolated from, but in thermal contact with the resistance wire

heater 46 located near the tip. Wire 48 and wire 50 couple the heater 46 to the electrical power source 52 which may be an AC or DC source which may be modulated to control the energy delivery to the tip.

Fig. 4 shows a laser-heated embodiment of the thermal catheter device 10. In this embodiment the tip 60 absorbs radiation from the optical wave guide 62 coupled to the laser source 64. In operation the laser energy source may operate continuously or intermittently to deliver energy to the tip 60. In operation the laser light impinges on the tip structure and it is absorbed and converted to heat. The distal tip 60 may be magnetic or may be made from a magnetically active material. In general, and depending on detail design issues the surface of the tip may or may not be electrically conductive. In this particular embodiment it should be clear that the thermal requirements of the tip are significant in contrast to other embodiments where electrical conductivity is critical. It is contemplated that the distal tip may be made of ceramic or "glassy" material.

Fig. 5 shows an embodiment of the invention wherein thermal catheter 10 has a distal tip 70 which has a tube 71 that has an open lumen 72 which communicates to the proximal end of the device. This lumen 72 can be used for several purposes. For example, the lumen can accommodate either an imaging wire 76, ultrasonic or laser imaging, or a guide wire 74. In operation the preferred ultrasonic imaging wire can be used to visualize and locate the occlusion. Once the occlusion has been located and characterized, the correct amount of power can be delivered to the distal tip 70. Typically the ultrasound imaging wire would be withdrawn and parked in the lumen 72 proximally to prevent heat damage to the transducer of the imaging wire. During device placement the lumen can be used with guide wire 74 to access the treatment site.

The lumen can also be used with an optical fiber to perform laser induced florescence spectroscopy or optical low coherence reflectometry or optical coherence tomography. These procedures can be used to "look at" and evaluate the obstruction during treatment.

Fig. 6 is an example of a "rapid exchange" delivery configuration for the thermal catheter 10. The distal tip 80 as an open lumen 82 which is relatively short and exits the side of the catheter body 84 at a location distal of the proximal end of the device 10. This opening can receive a guide wire which can be used to position the device near the occlusion.

Fig. 7 represents an ultrasound energy source catheter 92. The ultrasonic horn 94 is coupled to the waveguide 96 which in turn terminates in a distal tip 90. The waveguide may extend beyond the tip. In operation the delivery of ultrasound energy to the distal tip results in the formation of very small bubbles which dislodge the nearby plaque or other obstructing material. In this embodiment the distal tip 90 may be formed of Hiperco or other magnetically active material.

Fig. 8 represents a hydraulic catheter 91 which uses the force of a jet of fluid emerging from nozzle 93 to disrupt the occlusive material. In this device the distal tip 100 may be made from Hiperco or another magnetically active material.

Fig. 9 shows the device 10 of Fig. 5 located in a sheath 120. The space between the sheath and the catheter body 122 can be flooded with contrast agent to reveal the location of the catheter with respect to the occlusion. At some power levels the space can be used to conduct cooling fluid to the tip to help regulate the temperature and temperature distribution of the device 124. Saline injection can also be used to prevent implosion of vapors in the blood at the treatment site.

Fig. 10 shows the device 78 of Fig. 5 in a sheath that limits the movement of the distal tip 70. In this version of the device the sheath 130 positions the distal tip 70 near the guide magnets 134. This allows the physician to move the tip with the MSS and to control the exit of fluid from the sheath.

Fig. 11 represents a multi-lumen construction where a fluid supply lumen 140 is provided to irrigate the tip 144 of the catheter 146. An offset guide wire lumen 148 is provided for used with imaging and locating devices.

Fig. 12 shows an embodiment of the catheter where the fluid exiting the tip through a port 150 serves to cool the catheter body 152. In this device the exterior wall of the catheter forms a central lumen which may be filled with a cooling solution. In general this volume may be too large to use for contrast injection. The fluid pressure in this sheath could also be reversed to create a vacuum on the occlusive material and remove it from the body during ablation.

Fig. 13 is a schematic diagram of a MSS system for using the catheters in a patient. In operation the physician user interacts with the patient 302 and the workstation console 300. The software used by the workstation coordinates several separate sources of data and control certain hardware as well. For example information from a preoperative scan 305 is loaded into the workstation 300 to provide a template of the treatment site. This preoperative data may be collected from MRI, CT, ultrasound, or other diagnostic imaging scans. Real time biplane x-ray data is supplied by an x-ray machine 303 and 304 to the workstation as well for display against the template and for interaction with the physician. As an alternative, orthogonal coils 301 and 302 may be used with an RF location system to localize the position of the catheter.

In general a fiducial marker on the catheter allows the preoperative scan and the real time scans to be appropriately merged. In operation the user can define a location on the MSS workstation 300 with a mouse or other pointing device which identifies the desired location of the therapy. Next the MSS workstation computes the forces and required fields and gradients required to navigate the catheter to the new location. This information controls the magnet system 308. An appropriate set of catheter actuators 306 may be provided to allow the MSS to move the catheter as well.

A second embodiment of a magnetically guided atherectomy device is indicated generally as 400 in Figs. 14 – 16. The magnetically guided atherectomy device 400 comprises an elongate catheter 402, having a proximal end (not shown) and a distal end 406, with a lumen 408 therebetween. The catheter 402 can be made of any flexible, biocompatible material conventionally used for medical catheters, for example Pebax.

A support 410 is mounted in the lumen adjacent the distal end 406. This support 410 can be permanently affixed within the catheter 402, with only the distal portion of the support projecting beyond the distal end 406 of the catheter. The support 410 is preferably made of a transparent, biocompatible material, such as polyethylene, polycarbonate, Pebax, or other suitable material. The support 410 includes passages for the ablation electrode conductor, and imaging, and preferably also includes compartments for receiving magnet body as described in more detail below.

The magnetically guided atherectomy device further includes an ablation electrode 414, on the distal end of the support 412. The ablation electrode 414 has a smoothly contoured, rounded shape, with a radius of curvature selected to selectively heat the material in front of, and closely adjacent to, the ablation electrode. An electrode conductor 416 extends from the proximal side of the electrode 414, through a conductor passage 418 in the support 410 and through the catheter 402 to the proximal end.

One or more optical fibers terminate in the body, facing generally radially outwardly for imaging the vessel in which the device 400 is located. In this preferred embodiment there are two optical fibers 420 and 422, having beveled distal ends 424 and 426, respectively. The optical fibers 420 and 422 extend proximally to the proximal end of the catheter 402, where the optical fibers are connected an imaging system. The imaging system may be an optical imaging system, or preferably an optical coherence tomography system. Optical coherence tomography provides imaging capability within the blood vessel and has been used in navigable medical devices such as Colston et al., U.S. Patent No. 6,175,669, Tearney et al., U.S. Patent No. 6,134,003, Selmon et al., U.S. Patent No. 6,120,516, Gregory, U.S. Patent No. 6,117,128, Townsend et al., U.s. Patent No. 6,066,102, Whayne et al., U.S. Patent No. 6,047,218, Selmon et al., U.S. Patent No., 6,010,449, Selmon et al., U.S. Patent No. 5,968,064, Swanson et al., U.S. Patent No. 5,804,651, McGee, U.S. Patent No. 5,752,518, Hanson et al., U.S. Patent No. 5,741,270, McGee, U.S. Patent No. 5,722,403, the disclosures of which are incorporated herein by reference. The catheter 402 can be rotated, or the individual optical fibers 420 and 422 can be rotated to imaging substantially the entire (and preferably the entire) interior circumference of the vessel in which the device is located.

At least one magnet member is disposed in the distal end portion of the device 400. In this second preferred embodiment, there are two magnet members 432, each having a D-shaped transverse cross-section, and disposed in correspondingly shaped passages 434 in the support 410. The magnet members 432 may be made of a permanent magnetic material, for example a neodymium-iron-boron (Nd-Fe-B) material, or a permeable magnetic material such as hiperco. The magnet members are sized and shaped so that they tend to align the distal end portion of the device 400 with an externally applied magnetic field. Thus, through the application of the appropriate field with the magnet(s) of an external magnetic surgical system, the distal end of the device can be oriented in any selected direction.

The magnetically guided atherectomy device 400 is oriented in the desired direction by the application of the appropriate magnetic fields with the magnetic surgery system, and the device is advanced, for example by mechanically pushing the proximal end. When the device 400 encounters plaque or other atheramatous material, heat can be applied to the blockage to destroy it by applying energy to the electrode 414 via conductor 416. A grounding pad applied to the patient provides a current path. The current density is so great in the material immediately adjacent (within a few millimeters) the electrode 414 that the material heats up and is ablated, while the vessel walls and other tissues are not damaged.

Through a combination of localization, for example with bi-planar fluoroscopic imaging, and imaging, for example with OCT, the location and orientation of the device within the walls of the vessel, an image of the device and its position and orientation in the vessel can be displayed so that through a simply user interface, for example an interface that allows the user to "click" on a cross-sectional image of the device within a vessel, and cause a controller (for example a computer or other microprocessor based controller) to operate the magnetic surgery system to change the field to cause the device to move in the indicated desired direction, or to cause the device to move to the indicated desired position. Complex movement patterns can also be programmed, for example the physician could indicate a size and or shape for the lumen of the vessel, and through the processing of information obtained from the localization and imaging system the controller to automatically control the device 400 to clear the indicated size and shape.

A third embodiment of a magnetically guided atherectomy device is indicated generally as 500 in Figs. 17 – 19. The magnetically guided atherectomy device 500 comprises an elongate catheter 502, having a proximal end (not shown) and a distal end 506, with a plurality of lumens 508 therebetween. The catheter 502 can be made of any flexible, biocompatible material conventionally used for medical catheters, for example Pebax, and is preferably transparent.

There is a disc-shaped electrode 510 on the distal end of the catheter 502. The electrode 510 has an opening 512 therein, generally transverse to the plane of the disc. A conduit 514 can extend through a generally central passageway 516 in the catheter 502 and through the opening 512 in the electrode 510, to make an electrical connection with the electrode, and provide energy to the electrode 510 for ablating atheramatous material that the electrode contacts. In this preferred embodiment the conduit 514 can be extended relative to the distal end and/or the catheter can be retracted relative to the conduit 514 to leave the conduit 514 as a guide so that the catheter 500 can be quickly and easily navigated to the surgical site.

The ablation electrode 510 has a smoothly contoured, rounded shape, with a radius of curvature selected to selectively heat the material in front of, and closely adjacent to, the ablation electrode.

The catheter 502 includes passages for the conduit 514 and for optical fibers for imaging, and compartment for receiving magnet bodies as described in more detail below.

One or more optical fibers terminate in the catheter 502, facing generally radially outwardly for imaging the vessel in which the device 500 is located. In this preferred embodiment there are two optical fibers 518 and 520, having beveled distal ends 518 and 520, respectively. The optical fibers 522 and 524 extend proximally to the proximal end of the catheter 502, where the optical fibers are connected an imaging system. The imaging system may be an optical imaging system, or preferably an optical coherence tomography system. The catheter 502 can be rotated, or the individual optical fibers 518 and 520 can be rotated to imaging substantially the entire (and preferably the entire) interior circumference of the vessel in which the device is located.

At least one magnet member is disposed in the distal end portion of the device 500. In this second preferred embodiment, there are two magnet members 526, each having a D-shaped transverse cross-section, and disposed in correspondingly shaped passages 528 in the distal end of the device 506; . The magnet members 526 may be made of a permanent magnetic material, for example a neodymium-iron-boron (Nd-Fe-B) material, or a permeable magnetic material, such as hiperco. The magnet members 526 are sized and shaped so that they tend to align the distal end portion of the device 500 with an externally applied magnetic field. Thus, through the application of the appropriate field with the magnet(s) of an external magnetic surgical system, the distal end of the device can be oriented in any selected direction.

The magnetically guided atherectomy device is oriented in the desired direction by the application of the appropriate magnetic fields with the magnetic surgery system, and the device is advanced, for example by mechanically pushing the proximal end. When the device 500 encounters plaque or other atheramatous material, heat can be applied to the blockage to destroy it by applying energy to the electrode 510 via conduit 514. A grounding pad applied to the patient provides a current path. The current density is so great in the material immediately adjacent (within a few millimeters) the electrode 510 that the material heats up and is ablated, while the vessel walls and other tissues are not damaged.

Through a combination of localization, for example with bi-planar fluoroscopic imaging, and imaging, for example with OCT, the location and orientation of the device within the walls of the vessel, an image of the device and its position and orientation in the vessel can be displayed so that through a simply user interface, for example an interface that allows the user to "click" on a cross-sectional image of the device within a vessel, and cause a controller (for example a computer or other microprocessor based controller) to operate the magnetic surgery system to change the field to cause the device to move in the indicated desired direction, or to cause the device to move to the indicated desired position. Complex movement patterns can also be programmed, for example the physician could indicate a size and or shape for the lumen of the vessel, and through the processing of information obtained from the localization and imaging system the controller to can automatically adjust the magnetic surgery system to move the device to clear the indicated desired path.

A fourth embodiment of a magnetically guided atherectomy device is indicated generally as 600 in Figs. 20-21. The magnetically guided atherectomy device 600 comprises an elongate catheter 602, having a proximal end (not shown) and a distal end 606, with at least one lumen 608 therebetween. The catheter 602 can be made of any flexible, biocompatible material conventionally used for medical catheters, for example Pebax, and is preferably transparent.

There is a dome-shaped cutting head 610 on the distal end of the elongate catheter 602. The cutting head 610 has a centrally opening an annular cutting edge 612 aligned with the lumen of the catheter. The smooth, dome shape allows distal end of the device to be manipulated within the blood vessel without damaging the inside structure of the blood vessels. The opening allows material that has been cored from the blood vessel to pass through the cutting head 610 to the lumen of the catheter where it can be accumulated or flushed out of the system.

One or more optical fibers terminate in the body, facing generally radially outwardly for imaging the vessel in which the device 600 is located. In this preferred embodiment there is a single optical fiber 614, having a beveled distal end 616. The optical fiber extends proximally to the proximal end of the catheter 602, where the optical fiber is connected to an imaging system. The imaging system may be an optical imaging system, or preferably an optical coherence tomography system. The catheter 602 can be rotated, or the individual optical fiber 614 can be rotated to imaging substantially the entire (and preferably the entire) interior circumference of the vessel in which the device is located.

At least one magnet member is disposed in the distal end portion of the device 600. In this fourth preferred embodiment, there is a single magnet member 618, having a generally C-shaped transverse cross-section, and disposed in correspondingly shaped passages 620 in the distal end of the device 600. The magnet member 618 may be made of a permanent magnetic material, for example a neodymium-iron-boron (Nd-Fe-B) material, or a permeable magnetic material, for example hiperco. The magnet members are sized and shaped so that they tend to align the distal end portion of the device 600 with an externally applied magnetic field. Thus, through the application of the appropriate field with the magnet(s) of an external magnetic surgical system, the distal end of the device can be oriented in any selected direction.

The magnetically guided atherectomy device is oriented in the desired direction by the application of the appropriate magnetic fields with the magnetic surgery system, and the device is advanced, for example by mechanically pushing the proximal end. When the device 600 encounters plaque or other atheramatous material, the device is advanced against the material so that the head 610 cuts a passage through the

atheramatous. Through a combination of localization, for example with bi-planar fluoroscopic imaging, and imaging, for example with OCT, the location and orientation of the device within the walls of the vessel, an image of the device and its position and orientation in the vessel can be displayed so that through a simply user interface, for example an interface that allows the user to "click" on a cross-sectional image of the device within a vessel, and cause a controller (for example a computer or other microprocessor based controller) to operate the magnetic surgery system to change the field to cause the device to move in the indicated desired direction, or to cause the device to move to the indicated desired position. Complex movement patterns can also be programmed, for example the physician could indicate a size and or shape for the lumen of the vessel, and through the processing of information obtained from the localization and imaging system the controller to can automatically adjust the magnetic surgery system to move the device to clear the indicated desired path.

A fifth embodiment of a magnetically guided atherectomy device is indicated generally as 700 in Figures 22 – 25. A first alternate construction of the device 700 is shown in Fig. 22. The device 700 comprises a catheter 702 having a proximal end 704 and a distal end 706, and a lumen 708 therebetween. A rotatable cutting member 710, having a proximal end 712 and a distal end 714, is disposed in the lumen 708. The rotatable cutting member 710 comprises a flexible drive shaft 716, which may be for example a flexible coil, with a cutting head 718 thereon. The cutting head 718 has a distal annular cutting edge 720, and an axial passage 722 for receiving material "cored" by the annular cutting edge. The flexible drive shaft 716 is preferably surrounded by a sheath 724 to protect in the inner wall of the catheter 702.

In this first alternate construction of the fifth preferred embodiment the sheath 724 includes an optical fiber 726, having a bevel distal end 728, facing generally radially outwardly for imaging the vessel in which the device 700 is located. The optical fiber 726 extends proximally to the proximal end of the catheter 702, where the optical fiber is connected an imaging system. The imaging system may be an optical imaging system, or preferably an optical coherence tomography system. As the rotatable cutting member 710 rotates, the sheath 724 and the optical fiber rotates with it, and the imaging system acquires an image of substantially the entire (and preferably the entire) interior circumference of the vessel in which the device is located.

At least one magnet member is disposed in the distal end portion of the device 700. The magnet member can be disposed in the wall of the catheter 702, or somehow associated with the rotatable cutting member 718, such as by making the cutting member 718 out of a magnetic or a magnetically permeable material. The magnet member may be made of a permanent magnetic material, for example a neodymium-iron-boron (Nd-Fe-B) material, or a permeable magnetic material, for example hiperco.

A second alternate construction of the device 700' is shown in Fig. 23. The device 700' is similar in construction to device 700, and corresponding parts are identified with corresponding reference numerals. As shown in Fig. 23, the device 700' comprises a catheter 702' having a proximal end 704 and a distal end 706, and a lumen 708 therebetween. A rotatable cutting member 710', having a proximal end 712 and a distal end 714, is disposed in the lumen 708. The rotatable cutting member 710' comprises a flexible drive shaft 716, which may be for example a flexible coil, with a cutting head 718' thereon. The cutting head 718' unlike cutting head 718 of device 700, has an oblate spheroidal shape, i.e., it is generally football shaped, having a roughed distal surface for cutting atheramatous material.

In this second alternate construction of the fifth preferred embodiment the catheter 702' includes an optical fiber 726, having a bevel distal end 728, facing generally radially outwardly for imaging the vessel in

which the device 700' is located. The optical fiber 726 extends proximally to the proximal end of the catheter 702', where the optical fiber is connected an imaging system. The imaging system may be an optical imaging system, or preferably an optical coherence tomography system. As the rotatable cutting member 710 rotates, the catheter 702' can be rotated so that the imaging system acquires an image of substantially the entire (and preferably the entire) interior circumference of the vessel in which the device is located.

At least one magnet member is disposed in the distal end portion of the device 700'. The magnet member can be disposed in the wall of the catheter 702', or somehow associated with the rotatable cutting member 718', such as by making the cutting member 718' out of a magnetic or a magnetically permeable material. The magnet members may be made of a permanent magnetic material, for example a boron-iron-boron (Nd-Fe-B) material, or a permeable magnetic material, for example hiperco.

A third alternate construction of the device 700" is shown in Fig. 24. The device 700" is similar in construction to devices 700 and 700', and corresponding parts are identified with corresponding reference numerals. As shown in Fig. 24, the device 700" comprises a catheter 702" having a proximal end 704 and a distal end 706, and a lumen 708 therebetween. A rotatable cutting member 710", having a proximal end 712 and a distal end 714, is disposed in the lumen 708. The rotatable cutting member 710" comprises a flexible drive shaft 716, which may be for example a flexible coil, with a cutting head 718" thereon. The cutting head 718", like cutting head 718' of device 700', but unlike cutting head 718 of device 700, has an oblate spheroidal shape, i.e., it is generally football shaped, having a roughed distal surface for cutting atheramatous material. There is a sheath 720" surrounding the flexible drive shaft 716.

In this third alternate construction of the fifth preferred embodiment the sheath 720" includes an optical fiber 726, having a beveled distal end 728, facing generally radially outwardly for imaging the vessel in which the device 700" is located. The optical fiber 726 extends proximally to the proximal end of the catheter 702, where the optical fiber is connected an imaging system. The imaging system may be an optical imaging system, or preferably an optical coherence tomography system. As the rotatable cutting member 710" rotates, the optical fiber 726 rotates so that the imaging system acquires an image of substantially the entire (and preferably the entire) interior circumference of the vessel in which the device is located.

At least one magnet member is disposed in the distal end portion of the device 700". The magnet member can be disposed in the wall of the catheter 702, or somehow associated with the rotatable cutting member 710", such as by making the cutting head 718" out of a magnetic or a magnetically permeable material. The magnet members may be made of a permanent magnetic material, for example a neodymium-iron-boron (Nd-Fe-B) material, or a permeable magnetic material, for example hiperco.

A sixth embodiment of a magnetically guided atherectomy device is indicated generally as 800 in Figures 25 – 27. A first alternate construction of the magnetically guided atherectomy device is indicated generally as 800 in Fig. 26. The device 800 comprises a catheter 802, having a proximal end 804, and a distal end 806, and a lumen 808 therebetween. A laser ablation tool 810 is disposed in the lumen of the catheter 802. The laser can heat the material distal to the distal end directly or heat the tip to heat this material. The laser ablation tool 810 has a distal end 812, and a first lumen 814 opening at the distal end, for receiving an optical fiber 816 for conducting ablating laser energy to the distal end of the tool to ablate atheramatous material distal to the tool. The tool 810 also includes a passage 818 for accommodating a guide wire to facilitate the navigation and control of the device 800.

Magnet members can be provided in wall of the catheter 802, and/or a portion of the tool 810 can be made of a magnetic material, or a magnetically permeable material. In the first alternate construction shown in Fig. 25, an annular magnet member 820 is incorporated into the sidewall of the catheter 802.

As shown in Fig. 25, irrigating fluid can be delivered to the treatment site through the annular space between the catheter 802 and the tool 810.

A second alternate construction of the device of the sixth embodiment, indicated generally as 800' is shown in Fig. 26. The device 800' is similar in construction to device 800, and corresponding parts are identified with corresponding reference numerals. The device 800' comprises a catheter 802', having a proximal end 804, and a distal end 806, and a lumen 808 therebetween. A laser ablation tool 810 is disposed in the lumen of the catheter 802. The laser ablation tool 810 has a distal end 812, and a first lumen 814 opening at the distal end, for receiving an optical fiber 816 for conducting ablating laser energy to the distal end of the tool to ablate atheramatous material distal to the tool. The tool 810 also includes a passage 818 for accommodating a guide wire to facilitate the navigation and control of the device 800.

Magnet members can be provided in wall of the catheter 802, and/or a portion of the tool 810 can be made of a magnetic material, or a magnetically permeable material. In the second alternate construction shown in Fig. 26, magnet member 820' is incorporated into the tool 810, just proximal to the distal end. The magnet member 820 has passages therein for accommodating the optical fiber and the guide wire.

As shown in Fig. 26, irrigating fluid can be delivered to the treatment site through the annular space between the catheter 802 and the tool 810'.

A third second alternate construction of the device of the sixth embodiment, indicated generally as 800" is shown in Fig. 26. The device 800" is similar in construction to device 800, and corresponding parts are identified with corresponding reference numerals. The device 800" comprises a catheter 802, having a proximal end 804, and a distal end 806, and a lumen 808 therebetween. A laser ablation tool 810" is disposed in the lumen of the catheter 802. The laser ablation tool 810" has a distal end 812, and a first lumen (not shown) opening at the distal end, for receiving an optical fiber (not shown) for conducting ablating laser energy to the distal end of the tool to ablate atheramatous material distal to the tool. The tool 810 also includes a passage 818 for accommodating a guide wire to facilitate the navigation and control of the device 800. In addition the tool 800" has a closed loop path 822 for the circulation of cooling fluid to cool the distal end portion of the tool 810".

Magnet members can be provided in wall of the catheter 802, and/or a portion of the tool 810 can be made of a magnetic material, or a magnetically permeable material. In the third alternate construction shown in Fig. 27, magnet member 820" is incorporated into the tool 810, just proximal to the distal end. The magnet member 820" has passages therein for accommodating the optical fiber and the guide wire.

As was shown in Figs. 25 and 26, irrigating fluid can be delivered to the treatment site through the annular space between the catheter 802 and the tool 810'.